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Report Highlights:

Russia continues registration of Genetically Engineered (GE) crops for imports of food and feed in accordance with existing Russian legislation. As of mid-July 2015, Russia has twelve registered lines of GE corn, seven lines of GE soybeans, one sugar beet line, one rice line, and two lines of GE potatoes. There is a de-facto ban on registration of GE crops for cultivation because there is no administrative mechanism for such registration. The development of such an administrative mechanism, and beginning of registration of GE crops for cultivation was postponed till July 1, 2017. Given that the registration process is estimated to take 5-6 years, cultivation of GE crops in Russia cannot be expected before 2023-2024. Moreover, some industry analysts expect that the official beginning of registration process may be moved beyond 2017. The anti-GE public opinion is still strong, but with the reduction in disposable incomes of Russian consumers, purchasing decisions will be based on prices. Labeling and information for consumers on the presence of GE ingredients in food products is regulated by the technical regulations of the Customs Union. These regulations require that products sold in the CU member countries must be labeled if they contain the presence of over 0.9 percent of GE lines. The CU technical Regulation for GE feed has not yet been adopted. Feed sold in Russia do not require labeling. However registration of GE lines for use in feed is required if the presence of registered lines is over 0.9 percent and the presence of non-registered lines is over 0.5 percent.

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REPORT OUTLINE

Section I. Executive Summary:

In Russia there has been no progress in agricultural biotechnology since July 2014. Moreover, from the latter part of 2014 and early 2015, there were more heated discussions and draft federal legislation proposing a complete ban on GE crops and on food and feed products that contain GE components. By mid-July 2015, these proposals were either rejected or laid on the shelf, and in the end both the regulatory mechanism and the status of agricultural biotechnology in Russia remained the same as in 2014:

There is a de-facto ban on cultivation of GE crops in Russia. Two years ago, in September 2013, the Russian Government adopted Resolution 839 on GMO Registration for Environmental Release. In accordance with Resolution 839, the development of a mechanism for the registration of GE crops for cultivation was to be completed by July 1, 2014. However, this Resolution immediately stimulated a hot anti-GMO campaign in Russia. By spring 2014, a number of institutions became embroiled in the debate. This debate included the agrarian committees of both the lower (Duma) and the upper (Council of Federations), chambers of the Federation Assembly of the Russian Federation, Russia's major legislative body, the Ministry of Agriculture of the Russian Federation, several public organizations, and authorities of some Russian provinces. Several draft amendments to the Russian legislature on agricultural biotechnology were proposed, ranging from postponing the implementation of Resolution 839 by several years, to a complete ban on turnover of genetically engineered crops and products on the territory of Russia, including a ban on imports of such products, and criminal penalties for illegal growth and distribution of genetically engineered crops. The campaign ended in June 2014 when the Government postponed registration of GE crops for cultivation by 3 years, to July 1, 2017. However, this delay did not change the requirements for designated ministries and agencies to develop a mechanism for such registration. Given that the registration process is estimated to take 5-6 years, cultivation of GE crops in Russia cannot be expected before 2023-2024.

The registration of GE crops/lines/traits for imports for food and feed has continued. Moreover, since July 2014 imports of soybeans and soybean products and ingredients have increased, primarily due to an increase in soy imports from the United States. However, this increase has been attributed primarily to the Russian import substitution policy with efforts to further develop the poultry and livestock sector. In turn, there has been an increasing demand for high-protein feed for those sectors in Russia; rather than due to any change in the biotech policy.

GMO labeling requirements remain the same as last year, but in Russia penalties for violations in labeling of GE food have strengthened. Labeling and information for consumers on the presence of GE ingredients in food products is regulated by the technical regulations of the Customs Union (CU) on safety and labeling of food products. These regulations require that in the CU member states products must be labeled if the presence of GE lines is over 0.9 percent. In Russia, fees for violating this labeling requirements range from 20,000 rubles to 50,000 rubles for individual entrepreneurs, and from 100,000 rubles to 300,000 rubles for legal entities. The CU technical regulation for feed has not yet been adopted. Feed sold in Russia do not require labeling. However registration of GE lines for use in feed is required if the presence of registered lines is over 0.9 percent and the presence of non-registered lines is over 0.5 percent.

Strategy for development of agricultural biotechnology in the future. "The Comprehensive Program for the Development of Biotechnology in the Russian Federation through 2020" (BIO 2020) remains Russia's governmental guideline for the development of biotechnology. This Program BIO 2020 authorized different Russian Ministries to develop biotechnology in their appropriate spheres; including development of different branches of agricultural biotechnology, one segment of which is the "development and introduction of genetically modified plants in agriculture." Following the adoption of "BIO 2020" on April 24, 2012, the Ministry of Agriculture included "development of biotechnology" as one of the sub-programs in its "Agricultural Development Program in 2013 and through 2020." However, this sub-program covers development of biotech methods of processing of agricultural products, and not the development of GE crops.

The current economic situation in Russia curbs the development of agricultural biotechnology. The Russian Ministry of Economic Development (MED) has indicated that the Russian economy will decline in 2015. With a presumption that average annual oil prices will equal \$50 per barrel, MED expects GDP to contract by 2.8 percent. Given the tight federal budget, financing of research for development of Russian GE crops and even for development of mechanism and methods of monitoring of GE crops in the environment in the next couple of years is unlikely. Financing of the Ministry of Agriculture's subprogram "Technical modernization and innovative development" that covers all innovation projects including in agricultural biotechnology in 2015 was cut by almost 1 billion rubles (\$18 million¹) to 2.15 billion rubles (\$39 million). The funds cut from this fund were redistributed to more pragmatic production support programs. Currently, the Russian government is focusing on import substitution as a primary objective in the near-term. There are government measures in place to support local agricultural producers and infrastructure, to increase the volumes and quality of locally produced food products. The introduction of bio-engineered crops to Russian farmers in an administratively managed and legal manner is a long term and capital-intensive project. In the near future, development of agricultural genetically-engineered crops for cultivation is a low priority for the government. There is no information on participation of Russian private businesses in the financing of research in agricultural

¹ The exchange rate of Russian ruble as of end of June 2015, was 55 rubles per \$1.

biotechnology.

On the other hand, Russia will continue to use imported GE components for food and feed in order to maintain the stability of the food and feed supply. Russian MED expects domestic consumer prices to rise 11.9 percent, and real wages to decline by 9.6 percent over the course of 2015. One of Russia's major state banks, VTB Capital, reportedly estimated that 40 percent of Russian income was spent on foodstuffs in 2014, up from 36 percent in 2013. Given the economic volatility in the market and food price inflation, it remains to be seen to what extent Russian consumer demand will continue to contract. Due to this situation, the stability of the food and feed supply has become one of the priorities of the Russian government.

(Note: All Russian legislative and regulatory documents use the term GMO (genetically modified organisms) or GMM (genetically modified microorganisms) instead of genetically engineered (GE) organisms/microorganisms. Therefore, throughout this report, when referring to language in those documents, we will default to the terms as used in the document.)

Section II: Plant and Animal Biotechnology

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) PRODUCT DEVELOPMENT:

In Russia, the de-facto ban on genetically engineered (GE) crop cultivation continues. Russia does not have an official ban on the cultivation of GE seeds. However, because they have not yet developed a mechanism for the approval for release into the environment, cultivation of GE seeds and crops is not allowed. Moreover, the Russian State Duma, Russia's major legislative body, considered a draft law which would implement a complete ban of the cultivation of GE crops and breeding of GE animals in Russia. This draft passed the first hearing in the Duma in April 2015, but at its second reading in June 2015, the draft was rejected based on the absence of a legal mechanism for the control over the cultivation of GE crops. However, the measure has been supported by the top agricultural officials of the Russian Government, including Deputy Prime Minister Dvorkovich, who supports the idea of GE-free agriculture in Russia².

Some progress in Russian agricultural biotechnology policy was made in 2012 and 2013. In April 2012, Russia adopted the Comprehensive Program on the Development of Biotechnology through 2020 (BIO 2020)³. The program, BIO 2020, envisages the development of different branches of biotechnology, including agricultural biotechnology. In September 2013, the Government of the Russian Federation adopted Resolution No. 839 that ordered the Ministry of Agriculture, together with other administrative authorities, to develop the mechanism of such registration by July 1, 2014. The Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) at the Ministry of Agriculture was appointed the

³ For more information see FAS Moscow GAIN report <u>Development of Biotechnology in Russia through 2020</u>

² http://redirect.state.sbu/?url=http://www.interfax.ru/russia/448419

implementer of such registration. However, in June 2014, the date for implementation of Resolution 839 was delayed by three years to July 1, 2017⁴. As of mid-July 2015, the mechanism for registration of GE crops for release into environment has not yet been developed.

Russian scientists have continued some laboratory research on GE crops, but the research has not yet reached the stage of field trials. Although field trials are not technically prohibited, they need special permission from the Variety Testing Commission at the Ministry of Agriculture which is no longer granted. The adoption of BIO 2020 fanned expectations of Russian scientists in the field of biotechnology. Also, agricultural producers have expressed interest in GE crops, especially droughtresistant crops and crops that are better suited to minimum and no-till farming. Moreover, many scientists feel that there is a large potential market in Russia for these crops. However, scientists report that they cannot increase research and begin commercialization of these crops until Russia implements a mechanism for approval of GE crops for cultivation.

Given the current economic situation in Russia and the tight federal budget, financing of research for development of Russian GE crops, and even for the development of a mechanism and methods for monitoring, in the next couple of years is unlikely. The amendments to the Federal Law "On Federal Budget for 2015⁵" approved cuts in the subprogram "Technical and technological modernization, innovative development" by almost 1 billion rubles (\$18 million) to 2.15 billion rubles (\$39 million). This subprogram covers all innovation projects, including in agricultural biotechnology. There is no information on the participation of Russian private businesses in financing research in agricultural biotechnology.

In late 2013, the Russian Government merged three Russian Scientific Academies – the Russian Academy of Sciences, the Russian Academy of Agricultural Science, and the Russian Academy of Medical Science. The Russian scientific institute which has the lead on conducting GE crop research is the Russian Institute of Agricultural Biotechnology in the former Russian Academy of Agricultural Science. At the same time, most research facilities, institutes and laboratories, of these three academies were moved to the jurisdiction and management of a separate agency – the Federal Agency for Science Organizations at the Government of the Russian Federation (FANO) (http://fano.gov.ru/.) The impact this reorganization on FANO's function is not yet clear. However, it is unlikely that during the transitional period scientists will expand their research.

There is no information on the participation of Russian private business in research in the fields of agricultural biotechnology. In mid-2015, the Russian Innovation Center, "Skolkovo" was authorized to conduct research in the field of agricultural biotechnology. However, to date there is no information on when the center will begin its work on agricultural biotechnology, what resources will be utilized, and what concrete fields of research will be covered⁶.

⁴ For more information see FAS Moscow GAIN report GMO Registration for Cultivation Postponed

⁵ FAS/Moscow GAIN report: Agricultural budget 2015 6-24-2015.pdf

⁶ FAS/Moscow GAIN report: Russian Agricultural Policy and Situation Bi-Weekly Update 8 6-2-2015.pdf. Amendment to the Federal Law "On the Innovation Center "Skolkovo added agricultural biotechnology to the list of activities of this Center. The amendments first of all concern property rights on land and facilities of Skolkovo, agricultural biotechnology is only one-line added sentence, which does not specify the exact fields of agricultural biotechnology to be developed.

b) COMMERCIAL PRODUCTION:

Russia does not cultivate any GE crops, including GE seed production.

c) EXPORTS:

Some soybean meal exports from Russia may have GE lines. In the last two years Russia has increased its production of soybeans and corn, and increased its exports of these crops. Exports of corn increased from 0.45 million metric tons (MMT) in MY 2009/10 (for a total value of \$76 million) to 4.06 MMT (total value of \$843 million) in MY 2013/14. While there is no cultivation of GE crops in Russia, there are also no approved methods and/or laboratories for certification of GE-free production of corn and soybeans. Therefore, producers and exporters cannot register their crops as GE-free, and exporters are not paid the premiums for GE-free crops. Along with growth of soybean production in the Far East, Russia increased exports of soybeans from 105 metric tons (MT) in MY 2010/2011 to 160,669 MT in MY 2013/2014. All soybeans are considered as non-GE, but without lack of certification. In the last two years Russia also increased exports of soybean meal. The company "Sodruzhestvo" located in Kaliningrad oblast of the North-West of Russia is the major exporter of soybean meal in Russia, and its soybean meal is primarily a result of crushing of imported soybeans. Therefore, Russia's soybean meal exports may contain GE lines.

Table 1. Russia: Exports of products that may contain GE ingredients, June-May, 2009 – 2014 and June-Apr. 2014/15

	2009/10	2010/11	2011/12	2012/13	2013/14	06/13 - 04/14	06/14 - 04/15
Metric Tons							
Corn (HS Number 1005)	452,454	101,565	1,754,847	1,915,057	4,061,828	3,636,640	2,572,015
Soybeans (HS Number 1201)		105	713	29,934	160,669	25,641	25,544
Soybean meal (HS number 2304)	7,913	21,166	16,818	53,479	393,103	362,257	516,871
U.S. Dollars, 1,000							
Corn (HS Number 1005)	75,777	18,861	411,978	537,011	842,104	743,697	444,450
Soybeans (HS Number 1201)	109	214	7,937	48,574	9,388	9,333	69,468
Soybean meal (HS number 2304)	4,631	11,064	9,086	33,729	234,157	215,112	280,063

Source: Global Trade Atlas

d) IMPORTS

Russia imports GE crops, and processes products containing GE ingredients. Imports of GE planting seeds are not allowed since Russia does not allow cultivation of GE crops. Imports of GE processed products is allowed if these crops/products have been tested and registered in Russia for food and/or feed use (See paragraph APPROVALS in PART B of the report).

Russian Customs data does not separate GE products from non-GE products. However, most corn and soybeans imported into Russia, as well as products produced from imported corn and soybeans, may

contain GE crops and GE ingredients. In accordance with Russian and CU legislation, imported food products are considered non-GE if the presence of GEs does not exceed levels determined by Russian and CU legislation: not more than 0.9 percent of registered or non-registered GE lines in food products or ingredients, and not more than 0.9 percent of registered GE lines and not more that 0.5 percent of non-registered GE lines in feed or feed ingredients. For more information see section Plant Biotechnology Policy of the report.

Russia is increasing its poultry and swine production at large, integrated poultry and swine farms that use compound feed in the feeding rations. The demand for protein and energy ingredients, such as corn and soybeans/soybean meal is increasing. Russia is trying to increase domestic production of these crops, and in 2013 Russia's corn crop reached a record level of 11.6 MMT. In 2014, the corn crop was 11.3 MMT. Russian farmers continue to increase area sown to soybeans, and in 2014 the soybean crop reached an historic high level of 2.6 MMT. Despite increased domestic production of protein and high energy feed, such as soybeans and corn, Russia continues to import soybeans, corn, and products processed from these crops (Table 3).

The anti-GMO preference of Russian consumers can still influence imports of corn and soybean and their products, especially soybeans and soybean products. In general, the feed trade does not reflect any strong pro- or anti-biotech bias. However, some regional authorities and companies in the south of European Russia, including Belgorod oblast (Russia's major meat producer), have declared themselves GMO-free-zones and buy only non-GMO feed, which are more and more difficult to find in the market. These regions have increased their own production of soybeans, but these beans are usually more expensive than imported soybeans. The anti-GMO campaigns in 2008-2011, and in MY 2013/14, affected food processors' decisions. Importers of these commodities preferred certified non-GE products in order to meet consumers' preferences. Sodruzhestvo, Russia's major soybean crushing company that crush primarily imported beans, maintains separate facilities for GE and non-GE soybeans in Kaliningrad.

On June 24, 2015, President Putin signed decree No. 320 extending Russia's ban on the import of agricultural products from the United States, Canada, the European Union, Australia, and Norway for a year as of August 6, 2015. However, neither imports of corn, nor soybeans, nor products, are covered by this ban. However, the current, tight economic environment has led to a decrease in consumers' disposable income. Generally, when purchasing food products consumer have switched to cheaper products, including food products and feed with GE components. Russian food and feed processors now pay more attention to the price of ingredient than to its non-GE status.

Table 2. Russia: Imports of products that may contain GE ingredients, June-May, 2009 – 2014 and June-Apr. 2014/15

-	2009/1	2010/1	2011/ 12	2012/ 13	2013/14	06/13 - 04/14	06/14 - 04/15
Metric Tons							
Corn (1005)	43,548	101,07 1	44,261	58,517	52,119	51,205	41,097
- from the U.S.	2,308	3,402	4,969	7,192	5,308	4,831	3,047
Corn Groats and Meal (1103 13)	25,056	22,120	17,214	17,360	11,623	10,861	1,560
- from the U.S.	0	2	0	0	0	0	0

Corn Starch (1108 12)	7,803	10,035	12,306	17,310	13,877	13,060	17,716
- from the U.S.	6	0	90	319	36	34	0
Soybeans (1201)	1,027,9	1,025,6	798,74	646,03	1,703,60	1,553,0	1,909,2
	99	52	1	5	1	71	48
- from the U.S.	95,968	26,788	30,250	81,844	450,239	450,23 9	348,03 8
Soybean flour (1208 10)	2,089	1,651	1,248	1,215	707	667	205
- from the U.S.	-	-	-	-	-	0	0
Soybean Meal (2304)	399,21	455,14	583,23	498,95	594,148	558,53	454,02
- from the U.S.	52,160	46,023	1,646	18631	21,509	17,045	14,732
Soybean Isolates (from 3504)		13,525					
Total group 3504	46,333	49,620	53,595	55,512	55,194	50,765	51,523
- from the U.S.	209	559	362	220	296	251	349
1,000 US Dollars							
Corn (1005)	51,112	96,017	101,35 7	141,93 4	214,937	213,42	142,98 6
- from the U.S.	1,550	2,428	4,194	6,694	5,414	4,936	3,083
Corn Groats and Meal (1103 13)	7,285	8,134	7,165	7,714	4,757	4,455	760
- from the U.S.	0	6	0	0	0	0	0
Corn Starch (1108 12)	2,899	6,068	7,966	11,775	11,161	10,402	10,386
- from the U.S.	0	90	319	36	0	0	4
Soybeans (1201)	480,15	521,27	431,70	429,93	1,005,1	913,35	982,92
	0	1	0	5	47	4	0
- from the U.S.	42,497	15,836	15,064	50,919	261,380	261,38 0	157,52
Soybean flour (1208 10)	1,499	1,380	1,152	1,170	752	705	227
- from the U.S.	0	0	0	0	0	0	0
Soybean Meal (2304)	198,33	213,40	269,80	317,87	387,223	363,72	269,25
- from the U.S.	23,186	20,938	918	12,632	14,669	11,529	8,474
Soybean Isolates (from 3504)							
Total group 3504	108,11	114,41	134,99	146,46	153,889	139,98	144,86 0
- from the U.S.	811	1,726	1,288	1,113	3,730	1,428	1,850

Source: Global Trade Atlas

Russian imports of corn has stabilized in the last five years at 40,000 MT – 50,000 MT, except in 2010/11 when a low grain crop forced Russian poultry producers to increase imports of corn to 0.1 MMT. Along with increased domestic production of corn in 2013-2014, imports declined. Steadily increasing Russian poultry production and the development of a domestic soybean crushing industry has stimulated imports of soybean. In 2014/15 (11 months), Russia imported over 1.9 MMT of soybeans, 23 percent more than in the same period a year ago. Major suppliers of soybeans to Russia were Paraguay (1.03 MMT), Brazil (458,231 MT) and the United States (348,038 MT). Russia also continued purchasing soybean meal in large quantities: imports of soybean meal in 2014/2015 (11

months), was 454,024 MT, including 217,287 MT from Argentina and 149,128 MT from Brazil. Imports of soybean meal from the United States were 14,732 MT.

e) FOOD AID RECIPIENT COUNTRIES:

Russia is not a recipient of food aid.

PART B: Policy

a. REGULATORY FRAMEWORK:

i. **RESPONSIBLE GOVERNMENT MINISTRIES**

The following Russian ministries, agencies and services are responsible for development of Russian biotechnology policy, including agricultural biotechnology, and for control and surveillance over use of GE crops and products that are approved for food and/or feed use.

Federal Service for Surveillance in the Sphere of Human Rights Protection and Human Well-Being (Rospotrebnadzor) headed by the Chief Sanitary Doctor of the Russian Federation (web-site: http://rospotrebnadzor.ru/about/). Rospotrebnadzor has the following functions:

- Conducts state registration of new GE lines for food use and new food products containing GE organisms, including those that are imported into Russian for the first time;
- Conducts survey and control of turnover of GE food products in accordance with Russian and Customs Union legislation;
- Keeps the state register of GE food products allowed for sale, production and imports on the territory of the Russian Federation;
- Develops legislation on GE food products.
- Together with the Federal Service for Veterinary and Phytosanitary Surveillance at the Ministry of Agriculture monitors the influence of GE crops and products on people and environment.

Since the unified economic space within the Customs Union started on January 1, 2012, valid certificates and permits on the use of biotech food and biotech food ingredients are those that were issued for circulation on the territory of the Customs Union.

The Ministry of Agriculture of the Russian Federation (web-site: www.mcx.ru) participates in the development of agricultural biotechnology policy together with Ministry of Economic Development and Ministry of Science and Education of the Russian Federation. Its functions are the following:

- Overall policy development for the use of GE crop and organisms in agriculture. In accordance with the Government Resolution 839 of September 2013, amended in June 2014 (see below), by July 1, 2017, the Ministry of Agriculture shall develop regulations for use of GE crops in agriculture, including for cultivation.
- Overall legal regulation of veterinary and phytosanitary condition of agricultural production and use of agricultural products., including legal regulation aimed at mitigation of any negative effects of GE crops and organisms on agricultural animals, plants, the environment, agricultural raw products, processed

food products.

Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) is subordinated to the Ministry of Agriculture of the Russian Federation (web-site: http://fsvps.ru). The VPSS has the following functions:

- Conducts state registration of new GE lines for feed use and new feed containing GE organisms, including those that are imported into Russian for the first time;
- Issues certificates of registration for GE feed;
- Keeps the state registration of feed derived from GE crops;
- Surveys the safety of feed and feed additives derived from GE crops at all stages of production and turnover;
- In accordance with the Government Resolution 839 of September 2013, amended in June 2014 (see below), by July 1, 2017, together with the Ministry of Agriculture, VPSS shall develop regulations for use and monitoring GE crops, including for cultivation, and GE animals;
- Together with the Federal Service for Surveillance in the Sphere of Human Health monitors the influence of GE crops and animals and products on people and environment.

The Ministry of Industry and Trade of the Russian Federation (web-site:

http://www.minpromtorg.gov.ru) participates in the development of national standards and technical regulations which set requirements for biological safety of regulated items. This Ministry participates in development of technical regulations of the Eurasian Economic Commission (formerly - Customs Union);

Ministry of Economic Development of the Russian Federation (web-site: www.economy.gov.ru) since 2012 monitors the implementation of the Comprehensive Program on Development of Biotechnology in the Russian Federation through 2020 (more on the Program see FAS/Moscow GAIN report Program on Development of Biotechnology in Russia through 2020);

The Eurasian Economic Union replaced the Customs Union of Kazakhstan, Russia and Belarus (CU), and now unites Kazakhstan, Russia, Belarus, Armenia and Kyrgyzstan. The Union develops and adopts the common customs and technical regulations for all countries-members of the Eurasian Economic Union (web-site: www.eaeunion.org). For Armenia and Kyrgyzstan that joined the Union in 2015 there is a transitional period for adaptation to technical regulations of the CU.

ii. <u>LEGISLATION AND REGULATIONS</u>

As of July 2015, Russian legislation in the sphere of agricultural and food biotechnology still does not contain a comprehensive harmonized code of laws. The GOR Resolution 839 of September 23, 2013 not only concerned the release of GE crops into environment, but was an attempt to harmonize Russian legislation on biotechnology. However, its postponement to July 1, 2017 has left this legislation hanging. Federal laws, government resolutions, and technical regulations of the Customs Union and orders of the Chief Sanitary Doctor (the Head of the Federal Service for Surveillance in the Sphere of Human Rights Protection and Human Well-Being - Rospotrebnadzor) listed below regulate Russian agricultural biotech policy at present. These include laws on product registration and consumer information about GE ingredients in food products. Since Russia became a member of the Customs Union (now the Eurasian Economic Union) its trade legislation is subordinated to the legislation of the

Union. As of July 2012, the Customs Union adopted several technical regulations that concern agricultural biotechnology and consumer labeling, and on July 1, 2013, these technical regulations came to force. These are the following Technical Regulations of the Customs Union: Technical Regulation on Food Safety, Technical Regulation on Food Labeling, and Technical Regulation on the Safety of Grain. Another Custom Union Technical Regulation that will be important from the point of view of imports and turnover of GE feed is the Technical Regulation on Feed. However, this CU Technical Regulation is still under discussion.

Summary of current Russian laws and regulations that influence agricultural biotechnology:

Federal laws

- Federal Law No. 86-FZ of June 5, 1996, On the State Regulation in the Sphere of Genetic Engineering Activities" with amendments made in 2000 and in 2010. This is a foundational federal law on genetic engineering in Russia, but the law does not determine instruments for implementation. In 2010, an amendment authorized the Government to develop and adopt procedures for the release of the genetically modified organisms into the environment (Federal Law No 262-FZ of October 4, 2010, On Amendments to the Federal Law "On the State Regulation in the Field of Genetic Engineering".);
- Federal Law No 52-FZ of March 30, 1999, On the Sanitary-Epidemiological Well-being of the Population;
- Federal Law No. 29-FZ of January 2, 2000, On the Quality and Safety of Food Products with amendments made in 2001 2008;
- Federal Law No. 2300-1 of February 7, 1992, On the Protection of Consumers Rights with amendments. The amendment of October 25, 2007 sets the threshold for mandatory labeling of food ingredients made from biotech material at 0.9 percent. Prior to this amendment, trace amounts of biotech food ingredients required labeling;
- The Federal Law No. 7-FZ of January 10, 2002, On Environmental Protection, as amended by January 1, 2011. Article 50.1 Environmental Protection from Negative Biological Impact of Federal Law No. 7-FZ of January 10, 2002. The Article states: "it is prohibited to produce, grow and use plants, animals and other organisms not typical for natural ecological systems, or created artificially, without developing effective measures to prevent their uncontrolled reproduction, obtaining a positive state ecological expert's conclusion, and permission from the federal bodies of executive power that conduct the state management of environment, and other federal bodies of executive power in accordance with their competence and legislature of the Russian Federation."
- **NEW**: Federal Law No. 521-FZ of December 31, 2014 "On Amendments to the Codex of the Russian Federation on Administrative Violations." The amendments concern penalties for violations of mandatory requirements for labeling food products derived from genetically engineered organisms (referred to as "GMO" in the Russian documents) or containing such organisms. The <u>fines</u> for individual entrepreneurs are from 20 thousand to 50 thousand rubles (from \$364 to \$909), and for legal entities are from 100 thousand to 300 thousand rubles (from \$1,818 to \$5,455). The law also provides Rospotrebnadzor with the authority to develop

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⁷ As of end of June 2015 the exchange rate of Russian ruble is 55 rubles per \$1.

protocols on administrative violations in such cases and submit these cases for the consideration of the court.

Resolutions of the Russian Government

- Resolution of the Government of the Russian Federation No. 988 of December 21, 2000, On State Registration of New Food Products, Materials, and Goods with amendments. The resolution authorizes registration of GE foods;
- Resolution of the Government of the Russian Federation No. 120 of February 16, 2001, On State Registration of Genetically Modified Organisms and Registration Regulation. This Resolution enforced the state registration of GE organisms;
- Resolution of the Government of the Russian Federation No 26 of January 18, 2002, On the State Registration of GMO Feed;
- Resolution of the Government of the Russian Federation No. 422 of July 14, 2006 which transferred testing and registration of biotech feed from the Ministry of Agriculture of the Russian Federation to the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) at the Ministry of Agriculture of the Russian Federation.
- Resolution of the Russian Government No. 717 of July 14, 2012, "On the State Program for Development of Agriculture and Regulation of Agricultural and Food Markets in 2013-2020".
 The program outlines the main directions of development of agriculture and agricultural science, including biotechnology, although agricultural biotechnology is not a priority.
- Resolution of the Russian Government No. 839 of September 23, 2013, "On the State
 Registration of Genetically-Engineered-Modified Organisms Intended for Release into the
 Environment as well as Products Derived from the Use of Such Organisms or Containing Such
 Organisms". The Resolution approved the main directions of registration of genetically
 engineered organisms and orders ministries and federal bodies to update or develop procedures
 for the beginning of registration;
- Resolution of the Russian Government No. 548 of June 16, 2014, "On the Amendments to the Resolution No. 839 of September 23, 2013" postpones the implementation of Resolution 839 from July 1, 2014 to July 1, 2017.

Normative acts of government bodies

- Resolution of the Chief Sanitary Doctor of the Russian Federation (No 14 of November 8, 2011), On the Procedures of Sanitary-Epidemiological Expertise of Food Products from Genetically Modified Sources;
- Methodological directives on norms and methods for testing, identification and analyses of
 genetically modified foods, organisms and microorganisms. State standards for food products.
 These methods and standards may be developed by different organizations, but are usually
 approved by Federal Agency on Technical Regulation and Metrology of the Ministry of Industry
 and Trade of the Russian Federation;
- Order of the Ministry of Agriculture No. 466 of October 6, 2009 on approval of regulations for VPSS on the State Registration of Feed Derived from Genetic-Engineered-Modifies Organisms.

In accordance with GOR Resolution 839 of September 23, 2013, government bodies connected with agricultural biotechnology should have begun developing a coordinated set of regulatory documents for registration and monitoring of GE food, feed, and crops, including for cultivation. However, when the implementation of this resolution was postponed till July 1, 2017, development of such regulatory documents stalled. So far there is no information on adoption of any such documents. Moreover, constraints of the federal budget and reorganization of some research institutes may curb development and adoption of such documents in 2015 and 2016.

Decisions of the Customs Union

Since July 2010 the Customs Union adopted several technical regulations that have influenced agricultural and food biotechnology. These technical regulations came to force on July 1, 2013, and all regulations require marking the presence of GMOs on labels, and informing consumers in cases when food products are processed from or with the use of GMO even if there is no DNA's or proteins of GMO components in the marketed food products. For the unofficial translations of the CU technical regulations that cover food safety and labeling issues and that came to force on July 1, 2013 please see GAIN reports:

- RS1233 Customs Union Technical Regulation on Food Safety
- RS1250 Customs Union Technical Regulation on Safety of Grain
- RSATO1211Customs Union Technical Regulations on Food Products Labeling
- RS1326 Customs Union Technical Regulation on Fat and Oil Products
- RS1334 Customs Union Technical Regulation on Juice

The technical regulations of the Customs Union are mandatory for all members of the Eurasian Economic Union but there are transitional periods for the new members, such as Armenia and Kyrgyzstan. The summary of the CU technical regulations are below:

<u>CU Technical Regulation No 021/2011 on Safety of Food Products</u> (adopted in December 2011, came to force on July 1, 2013). The definition of GMO in this technical regulation is -"genetically modified (genetically engineered, transgenic) organisms" is "an organism or several organisms, any noncellular, unicellular or multicellular formations able for reproduction or transfer of genetic material differing from natural organisms obtained with the use of genetic engineering methods and (or) containing genetically engineered material including genes, their fragments or gene combinations." This Technical Regulation states the following:

- Food products can be processed only from GMO/GMM registered in the CU (Paragraph 9 of Chapter 2);
- If the producer did not use GMOs at processing of food products, the presence of 0.9 percent and less of GMOs is considered an adventitious, unavoidable presence, and products is not GE (Paragraph 9, Chapter 2);
- The use of GMO in baby food and in food for pregnant and nursing women is not allowed (Paragraph 1 of Article 8).

The testing and examination of presence of GMO in food products is based on the following state standards (GOSTs) and guidelines: GOST R 52173-2003 "Food Raw Material and Food Products. Methods for detection of genetically modified organisms (GMO) of plant origin", GOST R 52174-2003 "Biological Safety. Raw materials and food products. Methods for detection of genetically modified

organisms (GMO) of plant origin by using biological microchips" and MUK (methodological guidelines) 4.2.2304-007 "On surveillance over circulation of food containing GMO."

CU Technical Regulation No 022/2011 on Food Labeling (adopted in December 2011 and came to force on July 1, 2013). This technical regulation requires that food products with GMO shall be labeled, and determines the format of this labeling. The presence of 0.9 percent and less of GMO shall not be labeled, and the product is not considered as a genetically modified (GM) products. Labeling of food products as non-GMO is voluntary and the absence of GMO shall be proved and documented. For packaged food products requirements the labels shall contain information on the presence of food product ingredients obtained with the use of genetically modified organisms. The GMO ingredient is not excused from being listed in the compound ingredients of food products in cases when the mass of the compound ingredient is not more than 2 percent of the mass of the product (Paragraph 4.10). The information about the specific characteristics of food products, including absence of components obtained from GMO (or) with the use of GMO, shall be confirmed by proofs. Organizations or individual entrepreneurs releasing such food products for circulation in the unified customs area of the CU shall keep the documents with proofs of presence of specific characteristics of food products. The Technical Regulation on Food Labeling also has a special paragraph (4.11.) "Requirements for Specification of Information on Presence of Ingredients Obtained with the Use of Genetically Modified Organisms in Food Products in Food Products Labeling." The paragraph reads as following:

- 1. For food products obtained with the use of GMO, including those not containing deoxyribonucleic acid (DNA) and proteins, the following information shall be specified: "Genetically modified products" or "Products obtained from genetically modified organisms", or "The product contains components of genetically modified organisms". If the manufacturer did not use genetically modified organisms in the process of manufacturing food products, the content of GMOs of 0.9 percent or less is an accidental or technically irremovable impurity, and such food products shall not be referred to as food products containing GMOs. When labeling such food products, GMO presence shall not be stated;
- 2. The indication of the following information is obligatory for food products obtained from genetically modified microorganisms or with the use thereof (bacteria, yeast and filamentous fungi, the genetic material of which was modified with the help of genetic engineering methods) (hereinafter referred to as the GMM): a) For products containing living GMM "The product contains living genetically modified microorganisms"; b) For products containing unviable GMM "The product was obtained with the help of genetically modified microorganisms"; 3) For products freed from engineered GMM or for products produced with the help of components freed from engineered GMM "The product contains components obtained with the help of genetically modified microorganisms";
- 3. Labeling of food products shall not contain information on GMO presence with respect to the used processing aids, produced from or with the help of genetically modified organisms.

<u>CU Technical Regulation No 015/2001 on the Safety of Grain</u> (adopted in December 2011, came to force on July 1, 2013). The Technical Regulation determines requirements for information on grain/oilseeds during transportation either in bulk of in consumer packs (for feed purposes). Article 4 (Safety Requirements, paragraph 16) stipulates that grain transported unpackeged should be accompanied by shipping documents that ensure its traceability and provide information on GMOs if presence of GMOs is higher than 0.9 percent. ... For the grain obtained with the use of GMOs the

information should be given: "Genetically modified grain" or "grain obtained from the use of genetically modified organisms" or "grain contains components of genetically modified organisms", indicating the unique identifier of the transformation event. In addition, in the sanitary requirements for grain/oilseeds (MRLs of toxic elements, micotoxins, pesticides, radionuclide and pests) the technical regulation stipulates that grain/oilseeds (both for food and for feed use) may contain only registered GMO lines (registered in accordance with the legislation of the states, members of the CU), and in the GM grain presence of non-registered lines shall not exceed 0.9 percent "Grain may contain only those GMO lines that are registered in accordance with the legislation of member states of the Customs Union. In grain that contains a GMO presence of not more than 0.9 percent of non-registered GMO lines is allowed." The same state standards (GOSTs) as in Technical Regulation 021/2011 shall be applied (GOST R 52173-2003 and GOST R 52174-2003).

<u>CU Technical Regulation No. 024/2011 on Fat and Oil Products</u> (adopted December 2011, came to force on July 1. 2013). This technical regulation requires labeling of oil and fat products released into circulation for human consumption, and labels shall include information on the presence of GMOs.

<u>CU Technical Regulation No 023/2011 "On Fruit and Vegetable Juices and Their Products"</u> came to force on July 1, 2013. The CU Technical Regulation on Juices and their products bans the use of GMOs in baby food (fruit and vegetable juice products for babies) and requires state registration of any product that was processed using methods of genetic modification.

iii. GE CROPS/LINES REGISTRATION FOR FOOD AND FEED USE

Registration for Food Use (procedure)

Rospotrebnadzor registers biotech crops and ingredients for food use for Russia and for the Customs Union. The registration process remains the same as was stated in the Annual Biotechnology GAIN reports 2011-2014:

- The applicant submits an application and dossier to Rospotrebnadzor;
- Rospotrebnadzor assigns a safety assessment studies to the Institute of Nutrition (Federal State Budget Enterprise "Science and Research Institute of Nutrition"), which may coordinate some study with other Russian science institutes and laboratories in the field of biotechnology and microbiology;
- The applicant concludes an agreement for the food safety assessment with this Institute; and
- Based on the Institute's assessment, Rospotrebnadzor issues a certificate of registration and registers the product.

It takes 12 months to conduct laboratory tests required for the safety assessment and an additional two to three months to organize and prepare documents for the new GE crops. Registering food products and ingredients requires less time. However, registration is only granted if the biotech product contains biotech events that have already been registered. It is necessary to provide a copy of the event registration certificate in the application documents when registering food products or ingredients. Only those companies with registered crops for food-use in Russia can provide a copy of the crop registration certificate.

Since 2006, Rospotrebnadzor has registered food-use crops for an unlimited time period. Information on

GE crops registered for food-use for food products or an ingredient containing registered biotech ingredients is available on Rospotrebnadzor's website: http://fp.crc.ru/gosregfr/. The list of registered products contains all new food products, not only biotech products or products with biotech ingredients. There are several hundred different products and names. To find permitted food products for a specific crop, search for the name of the crop and the words "genetically modified."

Registration for Feed Use

Plant-origin feed imports no longer require a veterinary certificate but still require a letter stating that the feed is biotech free. Feed may be classified as biotech-free if presence of each non-registered biotech line in feed does not exceed 0.5 percent and if the presence of each registered biotech line in the feed does not exceed 0.9 percent. In this case, "registered" refers to products registered in Russia and "non-registered" refers to products not registered in Russia. The presence of genetic alterations in feed components is calculated separately and not comprehensively. For example, if two registered components in feed contain 0.6 percent of genetic alterations in each, then the feed is considered to be non-biotech, although together the sum is 1.2 percent. The pre-export identification of feed as non-GMO is not required. It is up to the producer/exporter to declare the feed as non-GMO, but VPSS regardless examines the products for the presence of GE components.

If the feed contains GE ingredients, and is not declared as biotech free, the shipment must include a copy of the certificate indicating that the biotech components in the feed are registered with the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS). The imports must also have a phytosanitary certificate, although this requirement is unrelated to biotechnology. Any biotech components in feed must be appropriately registered. Presence of each non-registered biotech line shall not exceed 0.5 percent. The Custom Union's Technical Regulation on Feed has not been adopted yet, but the draft has the same 0.5 percent norm of non-registered biotech lines as in the current regulations. However, the adopted Technical Regulation on Safety of Grain stipulates that feed grain/oilseeds is considered non-GMO if the presence of each non-registered biotech lines does not exceed 0.9 percent. The Technical Regulation on Safety of Grain came into to force on July 1, 2013.

The responsibilities of VPSS in feed registration were confirmed by the Order of the Russian Ministry of Agriculture No. 466 of October 6, 2009 that approved the regulations for registration. The Regulation states that the registration is issued for 5 years. The regulation covers "products of plant, animal and microbiological origin, and their components, used for feeding animals, and which contain animal health non-harmful digestible nutrients." The Regulation does not allow the registration of several types of GM feed under one name, or to register the same GM feed several times under one or under several different names. The applicant must submit the following documents:

1. application for the state registration of GE feed;

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⁸ VPSS regularly examines feed on the presence of GE components. Thus, in the end of June 2015, the Russian Federal Center of Quality and Standardization of Veterinary Pharmaceuticals and Feed (VGNKI) subordinated to VPSS conducted testing of 43 samples of feed originated from Ukraine (40 samples)/ Netherlands (2 samples) and Russia (1 sample) for the GMO content. Exceeded GMO content (more than 0.9%), GM soy line 40-3-2 was revealed in all samples. Therefore, all producers involved in the research violated requirements of the Russian Federation related to the GMO registration and labelling. VGNKI sent the results of tests to VPSS for the latter to take appropriate actions http://fsvps.ru/fsvps/news/14082.html. However, there is no information on what actions the VPSS have taken. Moreover, industry analysts consider that it is physically impossible to control GE in all feed, and that was one of the strong arguments of livestock and poultry lobby against the draft federal law that required ban on imports and circulation of GE food and feed in the Russian Federation.

- 2. materials that contain information on the following
 - information on the origin of GE feed,
 - evaluation of the potential danger of use of GE feed (compared with the initial basic feed), and recommendation of the applicant on the risk reduction,
 - information on the supposed use of the GE feed, and on the registration and the use of this feed abroad.
 - information about the technology of growing the modified variety of the plant that is used for production of GE feed,
 - data on the technology of production of GE feed,
 - draft of the instruction on the use of GE feed
- 3. if the modified plant variety, which is used for feed is viable and is meant for biomass or fodder growing, the certificate from the Russian State Register of Selection Achievements must be attached.

All documents shall be in Russian or shall have a certified translation into Russian. Copies of document shall be certified by a notary. VPSS will make a decision on the registration of a GMO feed based on the Conclusion of the Experts Council on the safety (non-safety) of the GMO feed. The procedure and necessary documents for registration of feed containing GMOs is on the VPSS's web-site: http://www.fsvps.ru/fsvps/regLicensing. The List of Registered GE feed (209 names as of July 7, 2015) is here. The site informs that beginning July 15, 2015, the register will be available on the site: www.galen.vetrf.ru.

To register formula feed, VPSS issues feed-registration certificates to a specific applicant for an individual shipment during a certain period of time. VPSS only issues certificates for feed produced using registered GE crops. The certificates cannot be transferred to different importers. This registration is conducted by VPSS.

The research of crops for feed use and the research of biotech formula feed before the approval is conducted by the Federal State Organization "All-Russian Center of Quality and Standardization of Animal Pharmaceuticals and Feed – VGNKI, subordinated to VPSS.

Fees for registration of biotech events (all fees are set in rubles):

Rospotrebnadzor's charges for all examinations and related services, including comprehensive studies required to register for food use biotech events. The fee varies, depending on the range of examinations and studies, but averages around 4.5 million rubles (approximately \$81,800) for the approval of new events for an unlimited period. The option to register for an unlimited period began in 2006. Registration of food products that contain a previously registered biotech event is 20,000 rubles (\$364).

For registration of biotech events for feed use, VPSS usually registers events only after it has been approved for food-use, although in some cases registration for feed use may precede registration for food. On average, the charge for examination and a 5 year event registration for feed use is 4.5 million rubles (approximately \$81,800). The charge for re-registration of the event every five years is 3.8 million rubles (approximately \$69,100). Companies that import formula feed with registered biotech components also need to register these feed as biotech feed. The registration is given to the company that imports this feed and VPSS requires that each feed that contains a registered GM event also be registered.

iv. RECENT ACTIVITIES OF RUSSIAN AUTHORITIES IN REGARDS TO GE CROPS

Since July 2014, there have been no changes to GE agricultural biotechnology legislation, except for increased fines for food labeling violations (see section "iii. Legislation and Regulations" of the present report). The government initiated the preparation to registration of GE crops for cultivation by its Resolution No 839 of September 23_2013. The Resolution described in detail what relative government bodies shall do in order to prepare regulations for systematized registration of GE crops. In pursuance of the Resolution 839 by mid-July 2014, ministries have drafted the following regulatory documents on the mechanism of registration:

- Ministry of Science and Education of the Russian Federation drafted the "Russian National Classifier of transformational events (genetic engineering)";
- The Ministry of Health drafted the Procedure of monitoring the unified register of GE organisms and products containing such organisms or derived from them;
- The Ministry of Agriculture drafted amendments to the status of the Ministry that will allow the Ministry to regulate processing of waste of agricultural production using different, including biotechnology, methods;
- The Ministry of Agriculture submitted for public comment (text is not available) the draft of Administrative Order "On approval of methodological guidelines for evaluation of risks and for risk management at the use (issuance) of genetic-engineered modified plants in/into the open systems."

FAS/Moscow informed on these preparatory steps in the <u>Agricultural Biotechnology Annual 2014</u>. However, so far none of these documents have been adopted, and their development stalled with the adoption of Resolution 839 and the registration of GE crops for cultivation was <u>postponed to July 1</u>, <u>2017</u>.

Despite postponement of implementation of Resolution 839, Russian mass media, some high level government officials, and members of the Federal Assembly, Russia's top legislative body, continued an anti-GE campaign. Thus, Arkadiy Dvorkovich, the Deputy Prime Minister who covers agriculture and related industries in the government, declared that Russia will not use GE crops in agriculture, that Russia has chosen "another way. We will not use these technologies" and that in the result Russian products "will be the cleanest in the world." Since July 2014, two legislative documents were drafted by members of Russian Duma, the lower chamber of the Federal Assembly and were discussed in the Duma:

- Draft federal law on amendments to the Federal Law "On Quality and Safety of Food Products" (draft federal law No. 460557-6). The draft proposed restrictions on the turnover of food products containing GE components and microorganisms. The draft was discussed at the first hearing on April 24, 2015, and the second hearing on June 9, 2015, and was rejected at the second hearing due to the strong opposition of scientists and food and feed industries. Their representatives claimed that the current methods of registration of GE lines for food and methods of control allow monitoring of turnover of food products, and any additional restrictions may disrupt food and feed supply;
- Draft federal law on ban of commercial cultivation of GE crops in Russia (draft federal law No. 714809-6 "On amendments to some legislative acts of the Russian Federation aimed at improvement

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⁹ http://www.interfax.ru/russia/448419

of state regulation in the sphere of genetic engineering") is still in the process of discussion. At the second hearing of this draft on June 15, 2015, the decision was made to postpone the consideration of this draft. So far it is not clear when the discussion of this draft will resume and what will be its future. The strongest argument for this delay was that so far there are no legally approved mechanisms, methods or institutions that are able to monitor release of GE crops into the environment.

Thus, so far, there have been no changes in the legislative documents that regulate registration of GE food, feed, and no clarity on the future of registration of GE crops for release into environment.

b) APPROVALS:

Since July 2014, Russia registered the following two new lines:

- Corn MON 89034 (Monsanto) was registered for food use (for feed this line was registered in March 2013,
- Soybeans FG72 (Bayer) was registered for feed use (for food use this line is still under review.

Besides, three lines already registered for food or feed use are expected to be registered for second use:

- Soybeans SYHT0H2 (Syngenta: Producers Syngenta /Bayer) line is expected to be registered for food use in 2015. For feed use this line was registered in April 2013;
- Soybeans MON 89788 (Monsanto) registration for feed use expired in May 2015, and at present the line is under review for extension of this registration. For food use this line was registered in 2010 for unlimited period;
- Soybeans FG72 (Bayer) line was submitted for registration for food use in December 2013, and is still awaiting approval. For feed use this line was registered in April 2014.

Since the beginning of registrations of biotech lines for food use in 1999, Russia has approved and registered 27 lines of GE crops. However, 3 lines such as Sugar beet line GTSB77 resistant to gliphosate, Potato RBBT02-06 resistant to Colorado beetle, and Potato SPBT02-5 resistant to Colorado beetle, were not re-registered because of the closure of the projects. Thus, as of July 1, 2015, Russia has 23 lines of biotech crops that can be legally imported to Russia for food use, and one additional line expects registration for food use in 2015. There are twelve lines of corn, seven soybean lines, one sugar beet line, one rice line, and two lines of potato. Of these 23 crops, 18 are also registered for feed use, including 11 lines of corn and 7 lines of soybeans. The list of registered crops is in the Table 2. Monsanto, Bayer, Syngenta and BASF were the only four companies to have their biotech crops registered in Russia, and BASF started registering its crops only in 2012/13. One registered sugar beet variety belongs to Monsanto and KWS.

Since 2007, food registration is given for unlimited period; however, the certificate of registration can be recalled if negative incidents occur. Feed registration is granted for five years.

Table 2. Russia: Approved and Registered Biotech Crops, 1999-2015

	Crop/line/event/trait	Applicant	Year and period of Registration		
			For Food Use	For Feed Use	
1	Bt corn MON 810, resistant to	Monsanto	2000 - 2003,	2003 - 2008	
	European corn borer Ostrinia		2003 - 2008	Sep. 2008 –	

	nubilalis		Mar. 2009 – for	Aug. 2013
	nuottatis		unlimited period	Aug. 2013 –
			ummica perioa	Sep. 2018
	Davidus Davidus NV 602	Managenta	2002 2007.	2003 – 2008
2	Roundup Ready® corn NK 603,	Monsanto	2002 – 2007;	
	tolerant to glyphosate		Feb. 2008 – for	Sep. 2008 –
			unlimited period	Aug. 2013
				Aug. 2013 –
_				Sep. 2018
3	Bt corn MON 863, resistant to	Monsanto	2003 - 2008	10
	corn root worm (Diabrotica spp.)		Aug. 2008 – for	
			unlimited period	
4	Corn Bt 11, tolerant to	Syngenta	2003 - 2008	Dec. 2006 –
	gluphosinate and resistant to corn		Sep. 2008 – for	Dec. 2011,
	borer Ostrinia nubilalis		unlimited period	Dec. 2011 –
				Dec. 2016
5	LL Corn T25, tolerant to	Bayer Crop	2001 - 2006,	Dec. 2006 –
	gluphosinate	Sciences	Feb. 2007 – for	Dec. 2011;
			unlimited period	Dec. 2011 –
				Dec. 2016
6	Roundup Ready ® corn GA 21,	Syngenta	2007 – for	Nov. 2007 –
	tolerant to glyphosate*		unlimited period	Nov. 2012;
			1	Nov. 2012 –
				Nov. 2017
7	Corn MIR 604, resistant to corn	Syngenta	Jul. 2007 – for	May 2008 –
	root worm (Diabrotica spp.)		unlimited period	May 2013;
	(May 2013 –
				May 2018
8	Corn 3272 with α-amylase	Syngenta	April 2010 – for	Oct. 2010 –
	enzyme to break starch during	Syngonia	unlimited period	Oct. 2015
	ethanol production		diffilition period	Oct. 2013
9	Corn MON 88017 (CCR),	Monsanto	May 2007 – for	Sep. 2008 –
	tolerant to glyphosate and	Wionsanto	unlimited period	Aug. 2013;
	resistant to corn root worm		diffiffica period	Sep. 2013 –
	(Diabrotica spp.)			Sep. 2013 – Sep. 2018
10	Corn MON 89034, resistant to	Monsanto	December 2014 –	Mar. 2013 –
10	· ·	ivionsanto	for unlimited	Mar. 2018
	Lepidoptera pest			IVIAI. 2018
1 1	Com MID 162 marietant to Dr. 1	Crus court -	period	March 1010
11	Corn MIR162, resistant to Broad	Syngenta	Apr. 2011 - for	March 1212 –
1.0	Lepidoptera spp.	G .	unlimited period	March 2017
12	Corn 5307, resistant to corn root	Syngenta	Apr. 2014 – for	Apr. 2014 –
1.5	worm (Diabrotica II, Coleoptera)		unlimited period	Apr. 2019
13	Roundup Ready® soybeans 40-3-	Monsanto	1999 - 2002,	2003 - 2008,

Registration for feed ended in August 2013, and Monsanto did not renew the registration for feed because discontinued production of these seeds. The registration for food remains because these seeds may still be under circulation in some countries, and traces of this corn may be found in commercial shipments.

	2, tolerant to glyphosate		2002 – 2007,	May 2008 –
			Dec. 2007 - for	May 2013
			unlimited period	May 2013 –
				May 2018
14	Bt soybeans, MON 87701,	Monsanto	May 2013 – for	Jul. 2013 – Jul.
	resistant to Lepidoptera pests		unlimited period	2018
15	Soybean MON 89788 (RRS2Y),	Monsanto	Jan. 2010 – for	May 2010 –
	tolerant to glyphosate + yield gain		unlimited period	May 2015
				Under review
				for extension
				since May
				2015
16	Liberty Link® Soybeans A2704-	Bayer Crop	2002 - 2007	Nov. 2007 –
	12, tolerant to gluphosinate	Sciences	2008 – for	Nov. 2012
			unlimited period	Nov. 2012 –
				Nov. 2017
17	Liberty Link® Soybeans A5547-	Bayer Crop	2002 - 2007	Nov. 2007 –
	127, tolerant to gluphosinate	Sciences	Feb. 2008 – for	Nov. 2012
	ammonium		unlimited period	Nov. 2013 –
				Nov. 2017
18	Soybeans FG72, tolerant to	Bayer	Under review,	Apr. 2014 –
	isoxaflutole and glyphosate		submitted in Dec.	Apr. 2020
			2013	
19	Soybeans BPS-CV-127-9,	BASF	Dec. 2012 – for	Sep. 2012 –
	imidazolinone		unlimited period	Sep. 2017
20	Soybeans SYHT0H2, herbiside	Syngenta	Submitted in April	Apr. 2013 –
	HPPD* + glufosinate	(Producers	2013; registration	Apr. 2019
		Syngenta /Bayer)	expected in 2015	
21	Rice LL62,	Bayer Crop	2003 - 2008	
	tolerant to gluphosinate	Sciences	Jan. 2009 – for	
	ammonium		unlimited period	
22	Roundup Ready ® Sugar beet	Monsanto/	May 2006 – for	
	H7-1, tolerant to glyphosate	KWS	unlimited period	
23	Bt potato "Elizaveta" (resistant to	Center "Bio-	Dec. 2005 – for	
	Colorado potato beetle)	engineering",	unlimited period*	
	<u> </u>	Russia		
24	Bt potato "Lugovskoy" (resistant	Center "Bio-	Jul. 2006 – for	
	to Colorado potato beetle)	engineering"	unlimited period	
*HP	PD – herbicides that inhibit the enzyl	me hydroxy-phenyl-	pyruvate-dioxygenase	

It is also expected that soybean line MON 87708, (Dicamba) (Monsanto) will be submitted for approval for food and feed use later in 2015.

In accordance with the CU Agreement on sanitary measures, since July 1, 2010, Rospotrebnadzor is registering food products produced on the basis of, or with use of GMO and/or GMM, for the whole

Customs Union (per Part II of the Unified List of Products Subject to sanitary-epidemiological surveillance on the customs territory and customs border of the CU, Decision of the CU Commission #299 of May 28, 2010.)

For feed, VPSS registers feed and additives only for five years. VPSS continues registration only for Russia. It is still not clear, when and how VPSS is planning to begin issuing certificates for biotech feed products valid on the territory of the whole Customs Union. The CU Technical Regulation on Feed is still under discussion, and has not been adopted.

c) FIELD TESTING

Not applicable. Since there is no legislation and no mechanism for release of GE crops into the environment, Russian researchers do not conduct wide scale field tests of GE crops.

d) STACKED EVENT APPROVALS

Russia approved stacked events for food and for feed use, but required registration of every trait separately. Thus, if the stacked event has three traits, the applicant shall submit documents for every trait, and shall register each trait and then the stacked event. So far Russia issued approvals for five stacked events: Corn Mon 88017 (CCR) approved for food and for feed use, Corn BT 11, approved for food and feed use, RR soybeans Mon 89788 (RRS2Y) approved for food and feed use, Soybean FG72 and Soybean SYHT0H2 are approved for feed use, but waiting approval for food use.

e) ADDITIONAL REQUIREMENTS:

None.

f) COEXISTANCE:

Not applicable since there is no mechanism and legislation for cultivation of GE crops.

g) LABELING

<u>Food labeling</u>: In accordance with the Technical Regulations of the Customs Union that came to force on July 1, 2013, all organizations that import, produce, or trade food products to/in the country-members of the Customs Union (Kazakhstan, Russia and Belarus) must inform consumers about the presence of biotech components in food products if each individual biotech event does not exceed 0.9 percent. In 2015, Armenia and Kyrgyzstan have become members of the Customs Union that was renamed into the Eurasian Economic Union. These two members shall also obey the requirements of CU technical regulations/ including technical regulations on labeling food products, after some transitional periods. The methods that should be used to test for biotech presence in food are also specified in the Attachments to the CU Technical Regulations on Food Safety and Food Labeling, and are the same that were used in Russia by Rospotrebnadzor before the CU Technical Regulations on Food labeling and Food Safety came into force.

For food products imported to Russia, Rospotrebnadzor has the right to conduct sample tests to detect the presence of biotech components. In order to verify the biotech-free claim, the producer or exporter may conduct its own tests at independent laboratories (it may be an IP system or PCR test), but the results of these tests are not accepted by the Russian Rospotrebnadzor. These pre-export tests are voluntary for producers and exporters. If a producer/exporter claims that its products are not genetically altered, Rospotrebnadzor still has the right to examine these products. Furthermore, if the presence of

genetic alteration in the products is more than 0.9 percent, a claim for fraud may be lodged on that company. Usually Rospotrebnadzor pays special attention to products containing soybean or corn ingredients. For more information on the CU's food labeling requirements please see section **Decisions** of the Customs Union above.

The Federal Law No. 521-FZ of December 31, 2014 "On Amendments to the Codex of the Russian Federation on Administrative Violations" specified the penalties for violations of requirements for labeling food products derived from genetically engineered organisms (referred to as "GMO" in the Russian documents) or containing such organisms. The <u>fines</u> for individual entrepreneurs are from 20 thousand to 50 thousand rubles (from \$364 to \$909), and for legal entities are from 100 thousand to 300 thousand rubles (from \$1,818 to \$5,455). The law also provides Rospotrebnadzor with the authority to draw up protocols on administrative violations in such cases and submit these cases to the consideration of the court.

<u>Feed labeling</u>: Information on composition of feed, including presence of biotech components is in the shipping documents, but so far Russia has not required labeling of presence of GMOs in feed on consumer packs of feed. The CU Technical Regulation on Feed is still under discussion, and has not been adopted. The requirements for information on GMO in shipping documents for grain and oilseeds and their products are in the CU's Technical Regulation on Safety of Grain. For more information please see section **Decisions of the Customs Union** above.

h) TRADE BARRIERS

Russia has a de-facto ban on cultivation of GE crops, and this impedes U.S. exports of planting seeds of crops, such as soybeans, rapeseed, sugar beets and corn. Russia's demand for efficient, drought-resistant varieties and hybrids of planting seeds of these crops is very high, but there is no open market for these seeds.

i) INTELLECTUAL PROPERTY RIGHTS (IPR):

Not applicable so far since there is no official information on the presence of GE crops in the fields of Russian farmers. However, this may become a serious issue if the illegal presence of GE crops is detected in Russian fields.

j) CARTAGENA PROTOCOL RATIFICATION:

Russian scientists understand the necessity to monitor biotechnology at the international level, including through measures envisaged by the Cartagena Protocol. However, Russia has not ratified this Protocol.

k) INTERNATIONAL TREATIES/FORA:

Russian participates in the APEC High Level Policy Dialogue on Agricultural biotechnology, in the meetings of the CODEX Alimentarius (Codex), and in the meetings of the International Plant Protection Convention (IPPC). Russia participated in the Global LLP Initiative in Rosario, Brazil, in September 2012, and also in some LLP events in 2013.

1) RELATED ISSUES:

Not applicable

1:

¹¹ As of end of June 2015 the exchange rate of Russian ruble is 55 rubles per \$1.

m) MONITORING AND TESTING

In Russia, Rospotrebnadzor monitors/tests GE food products and VPSS monitors/test grains, oilseeds for animal consumption and feed additives and ingredients (for more information see paragraph above on the role of different ministries and agencies).

n) LOW LEVEL PRESENCE POLICY

According to the CU Technical Regulations on safety of food products, grains and oilseeds, and on labeling requirements for food products, the presence of GE lines, components in food and feed shall be labeled or reported in accompanying shipping documents only if it exceeds 0.9 percent for food products and feed (for registered lines in feed), and 0.5 percent for non-registered lines in feed. However, these threshold levels do not mean that Russia has adopted or follow any coordinated LLP policy (for more information please see section of this report on CU Technical Regulations.)

PART C: Marketing:

a) MARKET ACCEPTANCE:

Labeling requirements increase the price of food containing GE ingredients. The price of examining products for the presence (or absence) of biotech components is high because the approved methods of testing are extensive. It is rare to find a GMO label in Russia, though non-GMO labels still can be seen on dairy, eggs and poultry products. In 2012, the Moscow city government stopped requiring non-GMO labeling 12, many food processors in Moscow discontinued these special tests on absence of GMOs, although some products are still sold with the special "Does not contain GMO" label. This is a voluntary, promotional label because Russia does not have standards for "organic" foods. Some food processors still prefer purchasing non-GE products, especially soybeans and soybean products. However, price is the dominant concern now both for food processors and consumers.

b) PUBLIC/PRIVATE OPINIONS:

There are no active pro-GE organizations, with the exception of a few select farmers' organizations and unions that are interested in increasing Russia's grain and oilseeds production. On the other hand, Russian Greenpeace and the Alliance of the CIS Countries "For Biosafety" (http://biosafety.ru) are very active in the anti-GMO campaigns. Even after postponement of registration of GE crops for cultivation for three years from July 2014 to July 2017, Russian anti-GE groups continued campaigning against GE crops. Public opinion in general reflects a negative attitude to GMOs. However, this negative opinion is seldom reflected in purchasing priorities of the Russian population, which are based on the price of products. The present economic situation in Russia (volatile rubles, decreased imports, high inflation, tight budget, decrease of purchasing power of Russian consumers) have resulted in cuts of financing of biotechnology research and development of GE-lines of Russian origin, on one side, and increased consumers' demand for cheaper products, on the other.

c) MARKETING STUDIES:

Not known.

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¹² FAS/Moscow GAIN Moscow Government Stops Requiring GMO-Free Labeling of Food Products

PART D: Capacity Building and Outreach:

In fall 2013 and all through the spring of 2015, the activities of anti-biotech groups increased and the anti-biotech campaign intensified. The penetration of agricultural biotechnology into Russia is presented as not only a threat for public health, but also as a threat to Russia's domestic agricultural production and food and national security. Pro-biotech groups and scientists have not received new funds in spite of a declared support of innovations and advanced technologies by the Russian Government. The program BIO 2020 envisages government advocacy of positive aspects and advantages of biotechnology, including agricultural biotechnology, but does not envisage any special funding for these activities.

CHAPTER 2: ANIMAL BIOTECHNOLOGY:

PART E: Production and Trade

- a. BIOTECHNOLOGY PRODUCT DEVELOPMENT: Research on GE animals was conducted in Russia under the guidance of Professor Lev Ernst, Academician of the Russian Academy of Sciences and the Russian Academy of Agricultural Sciences (he died in April 2012) in the cloning and genetic modification of animals immune to infection diseases. However, during the last three years there has been no information on the continuation of this research.
- b. COMMERCIAL PRODUCTION: Increased cattle production is one of the priorities of the Russian Government and it supports low interest rates on loans to livestock producers, including loans for importing pedigree breeding animals, semen and embryos. This support does not include any research on GE animals or clones.
- c. BIOTECHNOLOGY EXPORTS: Russia does not export any GE animals or livestock clones.
- d. BIOTECHNOLOGY IMPORTS: There is no information on any official restrictions on imports of GE animals or livestock clones. And there are no known facts of any imports of such products, even for research.

PART F: Policy

- a. REGULATION: Russia's Program BIO 2020, the road map for development of biotechnology is Russia is still valid. Agricultural biotechnology in this Program BIO 2020 is described as a section of biotechnology dealing with issues of theory, methodology and implementation of its achievements in plant and animal production", and is not the priority in this program. Moreover, in the State Program for Development of Russian agriculture in 2013, the development of biotechnology in animal and feed production envisages development of bio-additives for improvement of quality of feed amino-acids, feed protein, ferments, vitamins probiotics. But it includes no mention of GE animals or cloning.
- b. LABELING AND TRACEABILITY: Not applicable.
- c. TRADE BARRIERS: None

d. INTELLECTUAL PROPERTY RIGHTS:

Not applicable

e. INTERNATIONAL TREATIES/FORA:

Not applicable

PART G: Marketing

a. MARKET ACCEPTANCE:

Not applicable

b. PUBLIC/PRIVATE OPINIONS:

Not applicable

c. MARKET STUDIES:

There are no known market studies on the marketing of animal biotechnology products in Russia.

PART H: Capacity Building and Outreach

a. ACTIVITIES: None of the biotechnology-related capacity building activities with Russia had any component on animal biotechnology.

STRATEGIES AND NEEDS:

Currently none.